Truman J. Berst
37386 Soap Creek Road
Corvalis, Oregon 97330
(541) 791-8400

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

EUGENE DIVISION

UNITED STATES OF AMERICA, Case No: 6:11-cv-06370-TC

Plaintiff,

v.

TRUMAN J. BERST, an individual d/b/a ALTERNATIVE HEALTH & HERBS REMEDIES,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S OBJECTIONS TO MAGISTRATE'S FINDINGS AND RECOMMENDATIONS

COMES, the Defendant in the above-entitled action, Truman J. Berst, and responds to the Magistrates Findings and Recommendation by page number, *seriatim*:

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The Government's complaint is facially deficient, for the following reasons:

1. Defendant's products are not "new drugs."

> Under 21 U.S.C. § 321, Metabolife 356, as an herbal supplement, is a "food," not a "drug," and thus need not undergo the Food and Drug Administration's "new drug" testing policy found at 21 U.S.C. § 355.
>
> *Metabolife International, Inc. v. Wornick*, 264 F.3d 832, 837 n. 2 (9th Cir. 2001).

2. Painting black lines on the sides of a horse and calling it a zebra does not make it one. *United States v. Vazquez-Rivera*, 135 F.3d 172, 177 (1st Cir. 1998).

The first step to wisdom is calling a thing by its right name. *Roulette v. City of Seattle*, 97 F.3d 300, 307 (9th Cir. 1996).

3. Just as surely as Cinderella's step-sister could not make the fit, the Government has failed in its attempt to shoe-horn the word "drugs" onto "foods" that deliver a health benefit with consumption.

> The bending of the meanings of words is symptomatic of a diseased institution, with the angle of linguistic deflection indicating the seriousness of the cancer within. The Spanish Inquisition represented an advanced case.
>
> *Rawson's Dictionary of Euphemisms and Other Doubletalk*, Revised Edition, p. 35 (1995).

That is, the Governments's entire argument and position stems from a false premise.

"[P]roducts that constitute new drugs . . ."

"In July 2011, the FDA purchased ten of the products alleged to be drugs."

Apparently the Magistrate begins from the same false premise that the Government does.

Note that there were no consumer complaints, no allegations of harm to the public, nothing but the actions of Government employees attempting to justify their bloated paychecks *and* wasting taxpayer money into the bargain.

> The current per trial day cost is $ 17,500, *Beal Bank, Inc. v. Pittorino*, Civil Action No. 97-10927 (D. Mass. May 14, 1997) (transcript regarding sanctions) . . . . The $17,500 per day cost is an average for all cases.
>
> *United States v. Rostoff*, 966 F.Supp. 1275, 1287 n. 16 (D.Mass. 1997).

The first two paragraphs of this page appear to be mere boiler plate. Worse, the second paragraph appears to indicate that the Magistrate confused the litigants. Truman J. Berst is the *Defendant* in this action.

> Defendant does not challenge the allegation in the complaint that his products are not generally recognized among experts qualified by scientific training and experience to evaluate the

> safety and effectiveness of drugs, as safe and effective for those under the conditions prescribed, or suggested in their labeling.
>
> Magistrate's Findings and Recommendations, p. 3.

One does not have to be an "expert qualified by scientific training" in order to be able to understand what an herb is and what it can do. On the contrary:

> The leaves of these trees will never turn brown and fall, and there will always be fruit ... and the fruit thereof shall be for meat, and the leaf thereof for medicine.
>
> Ezekiel: 47:12.
>
> The Lord hath created medicines out of the earth; and he that is wise will not abhor them.
>
> Ecclesiasticus 38:4.

See also the Religious Freedom Restoration Act: 42 U.S.C. § 2000 *et seq.*, an issue studiously ignored by the Magistrate.

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The Magistrate ignores the issue that *other* sellers of herbal supplements are not being prosecuted. It is not the FDA that unjustly protects the pharmaceutical industry; it is the *people* running the FDA itself who are ignoring the intent of Congress, the will of the people, and the case

law in order to protect the pharmaceutical industry from competitors. See e.g., Reply from Congressman Peter DeFazio, attached hereto as Exhibit A.

> Indeed, the Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty. *Gonzales v. Carhart*, 127 S.Ct. 1610, 1636 (2007).
>
> Magistrate's Findings and Recommendations, p. 5.

There are a number of problems with that statement. It is an accurate statement of the case law:

> The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty. *See Kansas v. Hendricks*, 521 U.S. 346, 360, n. 3, 117 S.Ct. 2072, 138 L.Ed.2d 501 (1997); *Jones v. United States*, 463 U.S. 354, 364-365, n. 13, 370, 103 S.Ct. 3043, 77 L.Ed.2d 694 (1983); *Lambert v. Yellowley*, 272 U.S. 581, 597, 47 S.Ct. 210, 71 L.Ed. 422 (1926); *Collins v. Texas*, 223 U.S. 288, 297-298, 32 S.Ct. 286, 56 L.Ed. 439 (1912); *Jacobson v. Massachusetts*, 197 U.S. 11, 30-31, 25 S.Ct. 358, 49 L.Ed. 643 (1905); *see also Stenberg, supra*, at 969-972, 120 S.Ct. 2597 (KENNEDY, J., dissenting); *Marshall v. United States*, 414 U.S. 417, 427, 94 S.Ct. 700, 38 L.Ed.2d 618 (1974) ("When Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad").
>
> *Gonzales v. Carhart*, 127 S.Ct. 1610, 1636 (2007).

The primary problem here is this:

> In all Cases affecting Ambassadors, other public Ministers and Consuls, and those in which a State shall be Party, the supreme Court shall have original Jurisdiction. In all the other Cases before mentioned, the supreme Court shall have appellate Jurisdiction, both as to Law and Fact, with such Exceptions, and under such Regulations as the Congress shall make.
>
> Constitution Article III, Section 2, Clause 2.

I.e., the Congress does not need permission from the Supreme Court as to what it can and cannot legislate. The Constitution itself mandates the exact opposite conclusion ("under such regulations as Congress shall make") as does the case law:

As the Supreme Court has held:

> We must assume that, when the statute in question was passed, the legislature . . . was not unaware of these opposing theories, and was compelled, of necessity, to choose between them. It was not compelled to commit a matter involving the public health and safety to the final decision of a court or jury. It is no part of the function of a court or a jury to determine which one of two modes was likely to be the most effective for the protection of the public against disease.
>
> *Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905).

Congress may cure any error made by the courts. *Fast v. School District of City of Ladue*, 728 F.2d 1030, 1034 (8th Cir. 1984) (en banc).

Congress has the authority to over-rule wrongly decided cases. *Wesson v. United States*, 48 F.3d 894, 901 (5th Cir. 1995).

Congress has the power to counter judicial doctrine. *See Belgard v. State of Hawaii*, 883 F.Supp. 510, 514 (D. Hawaii. 1995).

The Magistrate has, in his words, "reviewed the statute." However, Defendant is more than a little bit skeptical regarding this statement. How much time did the Magistrate take to review the statute?

CONCLUSION

WHEREFORE, Defendant Truman Berst moves this Court to terminate this action and dismiss the FDA claims with prejudice.

Respectfully Submitted,

Dated: February 13TH, 2012

Truman J. Berst
37386 Soap Creek Road
Corvalis, Oregon 97330
(541) 791-8400